

Project/Program Title _____

Principal Investigator _____

VAMC _____ Review Date: _____

COMMITTEE FINDINGS:

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or a surrogate who possesses standard reading and comprehension skills. ☐ YES ☐ NO

2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. ☐ YES ☐ NO

3. Every effort has been made to decrease risk to subject(s)? ☐ YES ☐ NO

4. The potential research benefits justify the risk to subject(s)? ☐ YES ☐ NO

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met; a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) if an incompetent subject resists, he will not have to participate; d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described. ☐ YES ☐ NO

6. If the subject is paid the payment is reasonable and commensurate with the subject's contribution. ☐ YES ☐ NO ☐ NA

7. Members of minority groups and men have been included in the study population whenever possible and scientifically desirable. ☐ YES ☐ NO

8. Comments: (Indicate if Expedited Review)

RECOMMENDATION: ☐ APPROVE ☐ DISAPPROVE/REVISE

SIGNATURE OF CHAIRMAN

DATE